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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland

Re: **COMMENT ON FDA DRAFT FOR NEW GLOVE RULES**

Thank you for your request for information regarding the proposed FDA rule draft for medical glove regulations. I am a 30 year old Registered Nurse who has become asthmatic and **Type 1** latex allergic as a result of my occupational exposure to latex gloves. This condition has rendered me permanently disabled and unable to work in my field as well as in many other environments where latex gloves are used. I am happy to see that the FDA is addressing this public health issue. However, I feel that the most important issue as a professional nurse and as a healthcare consumer is patient safety, access to safe care for all latex allergic patients as well as patients that may potentially become sensitized to latex. I will respond based on the itemized requests.

1 Timeframe for implementation- I feel that a one year effective date is most desirable. The NIOSH issued recommendations regarding latex and powdered latex glove usage in 1991. Facilities and manufacturers have had 8 years to respond to this recommendation. This is a generous amount of time. Prolonging the proposed rule regulation for another year will only continue the adverse health concerns regarding medical gloves.

2 Recommended limit of no more than 120 mg of powder per powdered glove regardless of size Based on the plethora of scientific studies documenting the morbidity related to powdered medical exam gloves, i.e., aerosolization of allergens, wound infection and adhesions there is no sound reason to continue to use powdered medical exam gloves of latex or non-latex composition.

3 No comment 4 No comment

5 FDA considers a future requirement that all surgeons and patient exam gloves marketed in the US be powder free Agree to this requirement for the same reasons give in response to comment # 2.

6 FDA considers a restriction on the sale and advertising of powdered surgeons and patient exam gloves Agree to this restriction for the same reasons as comment #2 and #5.

7 FDA requests upper limit of protein per NL glove. This is a very difficult issue and one that should be based on suggestions from the leading researchers in latex allergy. I do not feel that I have the expertise or knowledge to suggest a limit. Common sense dictates that since latex proteins are responsible for serious and potentially fatal allergic reactions the lowest amount of protein per glove while maintaining barrier integrity should be mandated. This would decrease the risk of both the wearer and the patient becoming sensitized to NRL proteins or other adverse related conditions.

8 FDA requests for feasible alternatives approaches to reduce affects of allergic reactions and foreign body reactions Consider non-latex alternatives whenever possible when they provide equal or superior blood borne pathogen transmission. Require only powder free gloves, NRL or synthetic be used.

9 FDA requests whether limits on protein or powder should be recommended or required. As a patient and an employee that has been refused a reasonable accommodation (use of powder free gloves to decrease risk of airborne allergen) I feel that is imperative that powder free gloves be required. NIOSH and OSHA recommendations to use only low protein powder free gloves have been ignored by facilities and physicians because they are not required or mandated to use these products which are known to decrease the risk of sensitization and allergic reaction to airborne

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latex proteins. This has put patients and employees at increased unnecessary risk for serious allergic reactions and death. This is an unacceptable healthcare environment for patients and employees.

10 **No comment.**

11 **FDA considers the use of special air handling for facilities using gloves with greater than 120mg of powder**

Special air handling will help reduce the aerosolization of allergens. However, as stated previously I feel that "powder free" gloves are the only safe choice based on the scientific evidence of adverse health effects of powdered gloves.

This comment is not meant to support the use of any powdered medical glove.

12 **No comment**

Thank you for your interest in my comments. I hope my personal experiences will enable you to see how the proposed rule could protect the safety of the public at large and especially those persons already affect by latex allergy.

A handwritten signature in cursive script, reading "Jean M. Carazza-Mahoney". The signature is written in black ink and is positioned above the printed name.

Jean M. Carazza-Mahoney, BS RN

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